IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA RICHMOND DIVISION

Case No. 3:19-cv-00007

WILLIE CLAUDE PORTER,

Plaintiff,

v. **Civil Action No. 3:19-cv-0007**

DEPUY ORTHOPAEDICS, INC., et al.,

Defendants.

DEFENDANT'S ANSWER TO PLAINTIFF'S COMPLAINT

Defendant DePuy Orthopaedics, Inc., now known as Medical Device Business Services, Inc. ("DePuy") for its answer to Plaintiff's Complaint states as follows:

PARTIES

1. Willie Claude Porter (hereinafter "Plaintiff" or "Porter") is a resident and citizen of Wilson, North Carolina.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1, and therefore denies them.

2. Defendant DePuy Orthopaedics, Inc. (hereinafter "DePuy") is a corporation organized and incorporated in Indiana with its primary place of business in Warsaw, Indiana. DePuy developed, designed, tested, manufactured, distributed and sold the DePuy LCS Rotating Platform – Posterior Stabilized Knee System (hereinafter "LCS Rotating Platform Knee") that is the subject of this lawsuit.

ANSWER: Defendant admits that DePuy Orthopaedics, Inc., n/k/a Medical Device Business Services, Inc. ("DePuy"), is an Indiana corporation with its principal place of business located in Warsaw, Indiana. DePuy is in the business of developing, designing, testing, manufacturing, distributing and selling medical devices, including the LCS Rotating Platform Knee System. Defendant denies the remaining allegations in Paragraph 2.

3. Defendant DePuy, Inc. (hereinafter "DePuy") is a corporation organized and incorporated in Indiana with its primary place of business in Warsaw, Indiana. DePuy developed, designed, tested, manufactured, distributed and sold the LCS Rotating Platform Knee that is the subject of this lawsuit.

ANSWER: Plaintiff voluntarily dismissed his claims against DePuy, Inc. without prejudice and thus no response to Paragraph 3 is necessary.

4. Defendant DePuy Synthes Joint Reconstruction (hereinafter "DePuy") is a corporation organized and incorporated in Indiana with its primary place of business in Warsaw, Indiana. DePuy developed, designed, tested, manufactured, distributed and sold the LCS Rotating Platform Knee that is the subject of this lawsuit.

ANSWER: DePuy Synthes Joint Reconstruction, Inc. is a former name of DePuy Synthes Sales, Inc. Plaintiff voluntarily dismissed his claims against DePuy Synthes without prejudice and thus no response to Paragraph 4 is necessary.

5. Defendant DePuy Synthes Company (hereinafter "DePuy") is a corporation organized and incorporated in Indiana with its primary place of business in Warsaw, Indiana. DePuy developed, designed, tested, manufactured, distributed and sold the LCS Rotating Platform Knee that is the subject of this lawsuit.

ANSWER: Plaintiff voluntarily dismissed his claims against DePuy Synthes without prejudice and thus no response to Paragraph 5 is necessary.

6. Defendant DePuy International Limited (hereinafter "DePuy") is a corporation organized and incorporated in Indiana with its primary place of business in the United Kingdom. DePuy developed, designed, tested, manufactured, distributed and sold the LCS Rotating Platform Knee that is the subject of this lawsuit.

ANSWER: Plaintiff voluntarily dismissed his claims against DePuy International Limited without prejudice and thus no response to Paragraph 6 is necessary.

7. Defendant Johnson & Johnson (hereinafter "J&J") is a corporation organized and existing under the laws of New Jersey with its primary place of business in New Brunswick, New Jersey. As DePuy's parent company, J&J was involved in the development, design, testing, manufacture, distribution and sale of the LCS Rotating Platform Knee that is the subject of this lawsuit.

ANSWER: Plaintiff voluntarily dismissed his claims against Johnson & Johnson without prejudice and thus no response to Paragraph 7 is necessary.

8. Defendant Johnson & Johnson Services (hereinafter "J&J") is a corporation organized and existing under the law of New Jersey with its primary place of business in New Brunswick, New Jersey. As DePuy's parent company, J&J was involved in the development, design, testing, manufacture, distribution and sale of the LCS Rotating Platform Knee that is the subject of this lawsuit.

ANSWER: Plaintiff voluntarily dismissed his claims against Johnson & Johnson Services, Inc. without prejudice and thus no response to Paragraph 8 is necessary.

9. Defendant Johnson & Johnson International (hereinafter "J&J") is a corporation organized and existing under the law of New Jersey with its primary place of business in New Brunswick, New Jersey. As DePuy's parent company, J&J was involved in the development, design, testing, manufacture, distribution and sale of the LCS Rotating Platform Knee that is the subject of this lawsuit.

ANSWER: Plaintiff voluntarily dismissed his claims against Johnson & Johnson International without prejudice and thus no response to Paragraph 9 is necessary.

10. At all times mentioned, each of the Defendants was the representative, agent, employee, or alter ego and or dba of the other defendant and in doing the things alleged herein was acting within the scope of its authority as such.

ANSWER: Defendant denies the allegations contained in Paragraph 10.

11. DePuy and J&J are collectively referred to herein as "Defendants."

ANSWER: Defendant makes no response to rhetorical Paragraph 11, as it is purely explanatory in nature.

JURISDICTION

12. The court has personal jurisdiction over Defendants because Defendants are authorized to do business, and in fact, do business in Virginia. Defendants have sufficient minimum contacts with this state and otherwise purposefully avail themselves of the markets in Virginia through promotion, marketing, and sale of their products in the state.

ANSWER: Defendant admits that this court may properly exercise personal jurisdiction over the only remaining defendant, DePuy Orthopaedics, Inc. n/k/a Medical Device Business Services, Inc.

13. Venue is proper in this Court pursuant to 28 U.S.C. section 1391(a)(2) as a substantial part of the events giving rise to Plaintiff's claims occurred in the Eastern District of Virginia. Specifically, the defective knee replacement device distributed and sold by Defendants was placed in Plaintiff's body during a surgery at a hospital in the Eastern District of Virginia. Additionally, Plaintiff began experiencing significant problems with his failed knee device while still a resident of Virginia and sought follow up medical care and treatment with doctors in the Eastern District of Virginia.

ANSWER: Defendant admits that preferred venue exists in the United States District Court for the Eastern District of Virginia pursuant to 28 U.S.C. § 1391(a). Defendant denies all remaining allegations contained in Paragraph 13.

14. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. section 1332(a)(1) because the amount in controversy exceeds $75,000.00, exclusive of interest and costs and the parties are citizens of different states.

ANSWER: Defendant admits that this Court may properly exercise subject-matter jurisdiction over this case based upon the parties' diversity of citizenship and the amount of controversy.

INTRODUCTION

15. Defendants manufacture, market and distribute several different types of Knee Replacement Systems.

ANSWER: Defendant admits that DePuy Orthopaedics, Inc. n/k/a Medical Device Business Services, Inc. manufactures, markets, and sells various Knee Replacement Systems.

16. Some of Defendants Knee Replacement Systems include Fixed Bearing Knees, Rotating Platform Knees, and High Flexion Knees.

ANSWER: Defendant admits that DePuy Orthopaedics, Inc. n/k/a Medical Device Business Services, Inc.'s Knee Replacement Systems include various components but deny the remaining allegations contained in Paragraph 16.

17. The Rotating Platform Knees were designed to provide more natural movement, as the structural bearing can rotate in the same way as the original knee.

ANSWER: Defendant admits that one objective of a total knee replacement system is to replicate the natural movement and function of the knee.

18. Rotating Platform Knees models were designed to reduce stress and wear on the implant components.

ANSWER: Defendant admits that one objective of any total knee replacement system is to limit stress and wear on the system's components as much as practicable.

19. Defendant advertised the benefits of the Rotating Platform Knee as, less wear on the implants, more natural movement when compared to traditional knee replacements, and addressed patient's anatomical need for rotation.

ANSWER: Defendant admits that it advertised the benefits of the LCS Rotating Platform Knee System.

20. The rotating knee technology was pioneered more than 30 years ago by Defendants.

ANSWER: Defendant admits that it began manufacturing and selling total knee replacement systems more than 30 years ago.

21. Defendants marketed themselves as global leaders in hip, knee and shoulder replacement, and as the largest provider of orthopaedic and neurological solutions in the world.

ANSWER: Defendant admits that the allegations in Paragraph 21 are generally accurate.

22. Prior to 2012, Defendants were made aware of the tendency of many of their Knee Replacement Systems, including their Rotating Platform Knees to fail prematurely, causing patients extreme pain and tissue and bone damage.

ANSWER: Defendant denies the allegations in Paragraph 22.

23. These faulty Knee Replacement Systems require revision surgery, which is more complex, painful, and invasive than typical knee replacement surgery.

ANSWER: Defendant denies the allegations in Paragraph 23.

24. Defendants Knee Replacement Systems are marketed to last approximately 15 years. However, many reports show significant numbers of knee replacement failures only 1-2 years after the patients original surgery.

ANSWER: Defendant denies the allegations contained Paragraph 24.

25. Defendant has a long history with faulty joint replacement parts.

ANSWER: Defendant denies the allegations in Paragraph 25.

26. In the last several years, there have been multiple DePuy knee recalls for particular components of the Depuy Knee Replacement Systems.

ANSWER: Defendant denies the allegations in Paragraph 26.

FACTUAL BACKGROUND

27. On September 12, 2012, Plaintiff Porter underwent left total knee replacement surgery. As part of the knee replacement surgery, Porter's surgeon used the DePuy LCS Rotating Platform Knee.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 and therefore deny them.

28. In late 2013, approximately one year after his knee replacement surgery, Plaintiff Porter complained to his physician of unexplained and sudden pain and swelling in his left knee.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 and therefore deny them.

29. His physician referred him for physical therapy where he indicated that other than mild pain, he thought his left knee was ok. X-rays were taken of his knee and there was no evidence of loosening of the knee replacement system. However, some swelling was noted.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 and therefore deny them.

30. Plaintiff participated in physical therapy for several weeks before he was released.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 and therefore deny them.

31. Plaintiff Porter saw his physician several times between 2014 and 2016 complaining of continued and increased pain, swelling, stiffness and weakness in his left knee.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 and therefore deny them.

32. Plaintiff's treatment for his left knee problems during this time period included intermittent courses of physical therapy and cortisone shots.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 32 and therefore deny them.

33. In early 2017, Plaintiff began seeing a new orthopedic doctor regarding the pain, swelling and weakness in his left knee.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 33 and therefore deny them.

34. Plaintiff advised his new doctor that he had been having prolonged and significant pain and problems with his left knee for a long time.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 34 and therefore deny them.

35. After examining his left knee and taking x-rays, Plaintiff's doctor discussed knee replacement failure issues as a potential cause of his problems.

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 35 and therefore deny them.

36. He advised Plaintiff that the increased pain, swelling and other issues with his left knee could be the result of a mechanical loosening of the internal left knee prosthetic joint.

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 36 and therefore deny them.

37. The doctor's initial x-rays in early January 2017 showed no loosening of the left knee prosthetic. However, additional scans conducted later by Porter's doctor showed a possible loosening of the internal left knee prosthetic joint.

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 37 and therefore deny them.

38. Between February 2017 and July 2017, Plaintiff's doctor attempted to treat his left knee pain, swelling and discomfort with conservative measures. Nevertheless, Plaintiff's left knee issues continued to worsen.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 38 and therefore deny them.

39. On August 29, 2017, Porter underwent a total revision knee surgery. His physician noted that Porter presented with "pain, swelling and effusion in the left knee with documented infection." He also confirmed at that time that the indication for surgery was "the Left TKR with aseptic loosening of the femoral and tibial components."

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 39 and therefore deny them.

40. As a direct and proximate result of Defendants failed and defective knee replacement system, Plaintiff Porter was required to undergo a total knee revision surgery less than five years after his original knee replacement surgery.

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 40 and therefore deny them.

41. As a direct and proximate result of Defendants failed and defective knee replacement system, Plaintiff Porter suffered significant harm, conscious pain and suffering, physical injury and bodily impairment.

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 41 and therefore deny them.

42. As a direct and proximate result of Defendants failed and defective knee replacement system, Plaintiff Porter had to undergo a premature revision surgery of his prosthetic knee, causing further permanent impairment and weakness in his ligaments, bone and muscles.

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 42 and therefore deny them.

43. As a direct and proximate result of Defendants failed and defective knee replacement system, and the unexpected premature revision surgery, Plaintiff Porter may have to face additional knee replacement surgery in the future.

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 43 and therefore deny them.

44. As a direct and proximate result of Defendants failed and defective knee replacement system, Plaintiff Porter has suffered significant emotional distress and mental anguish, and will continue to suffer physical limitations, pain, injury, damages, harm and mental and emotional distress in the future.

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 44 and therefore deny them.

45. As a direct and proximate result of Defendants failed and defective knee replacement system, Plaintiff Porter has incurred medical expenses and will continue to incur such expenses in the future.

ANSWER: Defendant explicitly denies that its products were defective and injured Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 45 and therefore deny them.

COUNT I
(Negligence)

46. Defendant owed a duty to Plaintiff to use reasonable care in the manufacture, sale and distribution of the LCS Rotating Platform Knee. Defendant's proper performance of this duty would have eliminated the risk that the device Defendant distributed and sold would become unsafe for its intended use. Defendant breached this duty.

ANSWER: Paragraph 46 contains legal statements or conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 46.

47. Defendant had a duty to properly supervise, train, and monitor its employees, agents, and contractors to ensure their compliance with applicable statutes, laws, regulations, or safety codes pertaining to the manufacture, distribution, storage, and sale of the LCS Rotating Platform Knee. Defendant failed to do so and is therefore negligent.

ANSWER: Paragraph 47 contains legal statements or conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 47.

48. Defendant had a duty to use supplies and other constituent materials that were reasonably safe, free of defects, and in compliance with applicable federal, state and local laws, ordinances, and regulations. Defendant breached this duty.

ANSWER: Paragraph 48 contains legal statements or conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 48.

49. Defendant had a duty to ensure that the LCS Rotating Platform Knee it distributed and sold was safe for implantation in the human body. Defendant failed to do so and is therefore negligent.

ANSWER: Paragraph 49 contains legal statements or conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 49.

50. Defendant had a duty to exercise reasonable care to sell reasonably safe medical devices so as not to subject the ultimate consumer of the product to unreasonable risk of harm.

ANSWER: Paragraph 50 contains legal statements or conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 50.

51. Defendant was negligent, careless, reckless, grossly negligent and wanton, and breached its duties in manufacture, distribution and sale of the LCS Rotating Platform Knee in all of the following respects:

A. By manufacturing, inspecting, marketing, distributing, selling and/or supplying the LCS Rotating Platform Knee in such a way that persons using the product would be subjected to unreasonable danger;

B. By failing to warn hospitals and patients that the LCS Rotating Platform Knee was defective;

C. By placing and/or permitting the placement of the LCS Rotating Platform Knee into the stream of commerce when Defendant knew or should have known the it was defective;

D. By failing to employ corrective safety mechanisms to limit the harm caused by the LCS Rotating Platform Knee;

E. By manufacturing, inspecting, marketing, distributing, selling and/or supplying the LCS Rotating Platform Knee in an unsafe condition;

F. By failing to keep abreast of and/or react appropriately to public, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the LCS Rotating Platform Knee; and

H. By failing to use due care under the circumstances.

ANSWER: Defendant denies the allegations in Paragraph 51, including its subparts.

52. As a direct and proximate result of Defendant negligence, carelessness, recklessness, gross negligence and wantonness, Plaintiff has suffered injury and damages.

ANSWER: Defendant denies the allegations in Paragraph 52.

COUNT II
(Breach of Express Warranty)

53. Defendants made affirmations of fact or promises through the advertisement, labeling, marketing, and promotion of its product, the LCS Rotating Platform Knee, to health care professionals, the FDA, Plaintiff, and the public, representing that the LCS Rotating Platform Knee was safe, effective, fit, and proper for its intended use in order to induce its purchase or use, thereby making an express warranty that the LCS Rotating Platform Knee would conform to the representations.

ANSWER: Defendant denies the allegations in Paragraph 53.

54. Defendants' representations, mentioned above, related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

ANSWER: Defendant denies the allegations in Paragraph 54.

55. Defendants' LCS Rotating Platform Knee did not conform to their representations that the LCS Rotating Platform Knee was safe, effective, fit, and proper for its intended use.

ANSWER: Defendant denies the allegations in Paragraph 55.

56. At all relevant times, Plaintiff used the LCS Rotating Platform Knee for the purpose and in the manner intended by Defendants.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56.

57. Plaintiff and Plaintiff's physician, by the use of reasonable care, would not have discovered the breached warranty and realized its danger.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 57. Defendant explicitly denies that it breached any warranty or duty it owed to Plaintiff.

58. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

ANSWER: Defendant denies the allegations in Paragraph 58.

59. As a direct and proximate result of Defendants' actions, Plaintiff has suffered injury and Defendants are liable to Plaintiff for damages.

ANSWER: Defendant denies the allegations in Paragraph 56 as to liability. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 59.

COUNT III
(Breach of Implied Warranty Merchantability)

60. Defendants were and are merchants with respect to goods, such as the LCS Rotating Platform Knee.

ANSWER: Paragraph 60 contains legal statements or conclusions to which no response is required. To the extent a response is required, Defendant admits that DePuy Orthopaedics, Inc., n/k/a Medical Device Business Services, Inc. was involved in the design, development, and sale of the LCS Rotating Platform Knee. Defendant denies the remaining allegations in Paragraph 60.

61. Defendant impliedly warranted to Plaintiff that the LCS Rotating Platform Knee was fit for its ordinary purpose.

ANSWER: Defendant denies the allegations in Paragraph 61.

62. Defendant breached the implied warranty of merchantability because the LCS Rotating Platform Knee was dangerous and could not safely be used for its ordinary purpose.

ANSWER: Defendant denies the allegations in Paragraph 62.

63. Defendant knew or should have known that the LCS Rotating Platform Knee did not meet the capabilities as represented and marketed.

ANSWER: Defendant denies the allegations in Paragraph 63.

64. At all relevant times, Plaintiff used the LCS Rotating Platform Knee for the purpose and in the manner intended by Defendants.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 64.

65. Plaintiff and Plaintiffs physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 65. Defendant explicitly denies that it breached any warranty or duty it owed to Plaintiff.

66. Defendants' breach of the implied warranty was a substantial factor in bringing about Plaintiffs injuries.

ANSWER: Defendant denies the allegations in Paragraph 66.

67. As a direct and proximate result of Defendants' actions, Plaintiff has suffered injury and Defendants are liable to Plaintiff for damages.

ANSWER: Defendant denies the allegations in Paragraph 67 as to liability. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 67.

COUNT IV
(Breach of Implied Warranty of Fitness for a Particular Purpose)

68. Defendant knew that the LCS Rotating Platform Knee would be implanted and used in patients and that the physicians and patients were relying on its judgment to furnish suitable goods.

ANSWER: Defendant denies the allegations in Paragraph 68.

69. Defendant knew or should have known that the LCS Rotating Platform Knee did not meet the capabilities as represented and marketed.

ANSWER: Defendant denies the allegations in Paragraph 66.

70. At all relevant times, Plaintiff used the LCS Rotating Platform Knee for the purpose and in the manner intended by Defendants.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 64.

71. Plaintiff and Plaintiffs physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 71. Defendant explicitly denies that it breached any warranty or duty it owed to Plaintiff.

72. Defendants' breach of the implied warranty was a substantial factor in bringing about Plaintiffs injuries.

ANSWER: Defendant denies the allegations contained in Paragraph 72. Defendant explicitly denies that it breached any warranty or duty it owed to Plaintiff.

73. As a direct and proximate result of Defendants' actions, Plaintiff has suffered injury and Defendants are liable to Plaintiff for damages.

ANSWER: Defendant denies the allegations in Paragraph 67 as to liability. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 73.

COUNT V
(Strict Products Liability: Design Defect)
ORC §2307.75 et seq.

74. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of prosthetic devices including the LCS Rotating Platform Knee and all of its components for use in their total knee replacement systems.

ANSWER: Defendant admits that DePuy Orthopaedics, Inc., n/k/a Medical Device Business Services, Inc. was involved in the manufacture, design, distribution, and sale of prosthetic devices, including the LCS Rotating Platform Knee and its components. This Count asserts claims against Defendants arising under Ohio law and the Ohio Revised Code. The Defendant explicitly denies that Ohio law applies to this case given the facts alleged in Plaintiff's Complaint. Accordingly, Count V fails to state a claim as a matter of law.

75. The LCS Rotating Platform Knee, manufactured and supplied by Defendants was defective in design or formulation, in that when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, and/or it failed to comply with federal requirements for these medical devices.

ANSWER: Defendant denies the allegations in Paragraph 75.

76. The LCS Rotating Platform Knee was defective in design such that the risks of failure of loosening of the components of the rotating knee exceeded the benefits of the device.

ANSWER: Defendant denies the allegations in Paragraph 66.

77. The LCS Rotating Platform Knee was defective in design such that the failure of loosening of the components and the failure of the rotating knee was more dangerous than

a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

ANSWER: Defendant denies the allegations in Paragraph 77.

78. Defendants knew or should have known that the design of the LCS Rotating Platform Knee was faulty and would result in loosening and subsequent failure of the LCS Rotating Platform Knee.

ANSWER: Defendant denies the allegations in Paragraph 77.

79. The faulty components of the rotating knee rendered the LCS Rotating Platform Knee defective in its design.

ANSWER: Defendant denies the allegations in Paragraph 77.

80. The components of the LCS Rotating Platform Knee were defective in that at the time the product left the control of the Defendants, a practical and technically feasible alternative design was available that would have prevented the harm for which Plaintiff Porter seeks to recover without substantially impairing the usefulness or intended purpose of the product.

ANSWER: Defendant denies the allegations in Paragraph 80.

81. As a direct and proximate result of Plaintiff Porter's use of the LCS Rotating Platform Knee, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and Defendants failure to comply with the federal requirements, Plaintiff Porter suffered serious physical injury, harm and damages, and will continue to suffer such harm and damages in the future.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81 as to Plaintiff's injury, harm, and damages. Defendant denies the remaining allegations in Paragraph 81. Defendant denies that it failed to comply with any federal requirement and further denies that its products were defective or injured Plaintiff.

82. Defendants actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

ANSWER: Defendant denies the allegations in Paragraph 82.

COUNT VI
(Strict Products Liability: Defect Due to Nonconformance With Representations)
ORC §2307.77 et seq.

83. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of prosthetic devices including the LCS Rotating Platform Knee and all of its components for use in their total knee replacement systems.

ANSWER: Defendant admits that DePuy Orthopaedics, Inc., n/k/a Medical Device Business Services, Inc. was involved in the manufacture, design, distribution, and sale of prosthetic devices, including the LCS Rotating Platform Knee and its components. This Count asserts claims against Defendants arising under Ohio law and the Ohio Revised Code. The Defendant explicitly denies that Ohio law applies to this case given the facts alleged in Plaintiff's Complaint. Accordingly, Count V fails to state a claim as a matter of law.

84. The LCS Rotating Platform Knee, manufactured and supplied by Defendants was defective in that, when it left the hands of the Defendants, it did not conform to

representations made by Defendants concerning the product and/or with applicable federal requirements.

ANSWER: Defendant denies the allegations in Paragraph 84.

85. Plaintiff Porter and/or Plaintiff Porter's physicians, at the time they selected the LCS Rotating Platform Knee to be used in Plaintiff's surgery, justifiably relied upon Defendants representations that the LCS Rotating Platform Knee was safe for use in knee replacement surgery and would conform to the representations regarding the character and quality of an appropriate rotating knee to be used in knee surgery replacement.

ANSWER: Defendant denies the allegations in Paragraph 85.

86. As a direct and proximate result of Plaintiff Porter's use of the LCS Rotating Platform Knee, and Plaintiff Porter and Plaintiff Porter's physicians reliance on Defendant's representations regarding the character and quality of the LCS Rotating Platform Knee, Plaintiff Porter suffered serious physical injury, harm and damages, and will continue to suffer such harm and damages in the future.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 86 as to Plaintiff's injury, harm, and damages. Defendant denies the remaining allegations in Paragraph 86. Defendant explicitly denies that it products were defective and injured Plaintiff.

87. Defendants actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

ANSWER: Defendant denies the allegations in Paragraph 87.

COUNT VII
(Punitive Damages under Common Law)

88. Plaintiff is entitled to punitive damages because the Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the LCS Rotating Platform Knee and by failing to provide adequate instructions and training concerning its use.

ANSWER: Defendant denies the allegations in Paragraph 88.

89. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the LCS Rotating Platform Knee despite available information demonstrating that the components of the LCS Rotating Platform Knee could loosen and separate, causing serious harm to patients. Such risks and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious risks associated with the LCS Rotating Platform Knee or provided proper training and instruction to physicians regarding use of the LCS Rotating Platform Knee.

ANSWER: Defendant denies the allegations in Paragraph 89.

90. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of the LCS Rotating Platform Knee.

ANSWER: Defendant denies the allegations in Paragraph 90.

91. Defendants were or should have been in possession of evidence demonstrating that the components of the LCS Rotating Platform Knee were prone to loosening causing serious side effects. Nevertheless, Defendants continued to market the LCS Rotating Platform Knee by providing false and misleading information with regard to its safety and efficacy.

ANSWER: Defendant denies the allegations in Paragraph 91.

92. Defendants failed to provide warnings that would have dissuaded healthcare professionals from using the LCS Platform Knee, thus preventing healthcare professionals and consumers, including Plaintiff, from weighing the true risks against the benefits of using the LCS Platform Knee.

ANSWER: Defendant denies the allegations in Paragraph 92.

93. Defendants failed to provide adequate training and instructions to physicians that could have prevented failure of the LCS Platform Knee causing serious harm and suffering to patients, including Plaintiff Porter.

ANSWER: Defendant denies the allegations in Paragraph 93.

94. As a direct and proximate result of Defendants' actions, Plaintiff Porter has suffered injury and Defendants are liable to Plaintiff Porter for damages.

ANSWER: Defendant denies the allegations in Paragraph 94 as to liability. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 94.

SEPARATE DEFENSES

Defendant also asserts the following separate defenses. By alleging the separate defenses set forth below, Defendant is not in any way agreeing or conceding that it has the burden of proof or the burden of persuasion on any of these issues.

FIRST SEPARATE DEFENSE

Plaintiff's Complaint fails, in whole or in part, to state a claim upon which relief may be granted.

SECOND SEPARATE DEFENSE

The injuries and damages claimed by Plaintiff, if any, were or may have been caused, in whole or in part, by the acts or omissions of persons over whom Defendant has no control or right of control.

THIRD SEPARATE DEFENSE

Plaintiff would or may be barred from recovery to the extent that he was negligent, careless, and at fault and conducted himself so as to contribute substantially to his alleged injuries and damages.

FOURTH SEPARATE DEFENSE

Plaintiff knowingly and voluntarily assumed any and all risks associated with the use of the products at issue in this case, and such assumption of the risks bars in whole or in part the damages Plaintiff seeks to recover herein.

FIFTH SEPARATE DEFENSE

Plaintiff's alleged damages, if any, are or may be barred in whole or in part by Plaintiff's failure to mitigate such damages.

SIXTH SEPARATE DEFENSE

Plaintiff's claims are barred, in whole or in part, because the product at issue was at all relevant times manufactured and sold consistent with available technology, scientific knowledge, and the state of the art, and in compliance with all federal, state, and local laws and regulations, and was accompanied by product information and warnings that were reasonable, full and adequate and in accordance with FDA regulating requirements and the state of medical and scientific knowledge then in existence.

SEVENTH SEPARATE DEFENSE

If Defendant's products are unsafe in any way, they are unavoidably unsafe, and Plaintiff's purported action would or may be barred by Comment k of § 402A of the Restatement (Second) of Torts and/or other applicable law.

EIGHTH SEPARATE DEFENSE

Any alleged conduct or actions of the Defendant was not the proximate or producing cause of Plaintiff's alleged injuries or damages.

NINTH SEPARATE DEFENSE

Plaintiff's alleged injuries and damages attributable to the use of the products at issue in this case, if any, were not legally caused by the products at issue, but instead were or may be have been legally caused by intervening and superseding causes or circumstances.

TENTH SEPARATE DEFENSE

If Plaintiff incurred any injuries or damages as a result of the use of the products at issue, which Defendant denies, such injuries or damages were or may have been due to an idiosyncratic or idiopathic reaction, or by an unforeseeable or pre-existing condition.

ELEVENTH SEPARATE DEFENSE

Plaintiff's claims and causes of action are preempted by Medical Device Amendments to the Federal Food, Drug & Cosmetic Act and the FDA regulations promulgated pursuant thereto.

TWELFTH SEPARATE DEFENSE

Plaintiff's causes of action are or may be barred, in whole or in part, by the applicable statutes of limitation, statutes of repose, and/or doctrine of laches.

THIRTEENTH SEPARATE DEFENSE

Plaintiff's causes of action are barred by the doctrines of informed consent, release, and waiver.

FOURTEENTH SEPARATE DEFENSE

Plaintiff's causes of action are barred by the learned intermediary doctrine and/or the sophisticated user doctrine.

FIFTEENTH SEPARATE DEFENSE

Defendant did not make to Plaintiffs nor did it breach any express or implied warranties and/or breach of any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are or may be barred by applicable law, and for lack of privity with Defendant and/or failure of Plaintiffs, or Plaintiff's representatives, to give timely notice to

the Defendant of any alleged breach of warranty. Defendant further specifically pleads as to any breach of warranty claim all defenses under the Uniform Commercial Code existing and which may arise in the future as enacted in the Commonwealth of Virginia or any other state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

SIXTEENTH SEPARATE DEFENSE

Plaintiff's claims of product defects are barred by Sections 2, 4, and 6(c) and (d) of the Restatement (Third) of Torts: Products Liability.

SEVENTEENTH SEPARATE DEFENSE

Plaintiff's claims should be diminished in whole or in part in the amount paid to Plaintiffs by any party or non-party with whom Plaintiffs have settled or may settle.

EIGHTEENTH SEPARATE DEFENSE

Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

NINETEENTH SEPARATE DEFENSE

Defendant is entitled to, and claim the benefits of, all defenses and presumptions set forth in or arising from any rule of law or statute in any state whose law is deemed to apply in this case.

TWENTIETH SEPARATE DEFENSE

Plaintiff's claims are or may be barred by the equitable doctrine of estoppel.

TWENTY-FIRST SEPARATE DEFENSE

Plaintiff's alleged injuries are or may be a result of pre-existing and/or unrelated medical conditions for which Defendant is not responsible.

TWENTY-SECOND SEPARATE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

TWENTY-THIRD SEPARATE DEFENSE

To the extent that the products at issue in this lawsuit were changed, altered, or modified after they left the control of the manufacturer, such change, alteration, or modification was the legal cause of Plaintiff's injuries and damages, if any.

TWENTY-FOURTH SEPARATE DEFENSE

Plaintiff's product liability claims are barred because the benefits of the relevant products outweighed the risk.

TWENTY-FIFTH SEPARATE DEFENSE

Any claim for punitive or exemplary damages against Defendant is or may be unconstitutional in that recovery of punitive or exemplary damages in this case would or may violate Defendant's constitutional rights to due process and equal protection under the Fourteenth Amendment to the Constitution of the United States and similar protections afforded by the Virginia and Indiana state constitutions, and any other state whose law is deemed to apply in this case, and that any law of the Commonwealth of Virginia, whether enacted by the state's legislature or founded upon a decision or decisions of the courts, or that of any other state whose

law is deemed to apply in this case, that would permit recovery of punitive or exemplary damages, is or may be unconstitutional under these provisions.

TWENTY-SIXTH SEPARATE DEFENSE

Any claim for punitive or exemplary damages against Defendant is or may be unconstitutional in that the standards for granting and asserting punitive or exemplary damages do not prohibit other plaintiffs from seeking and recovering such damages against Defendant for the same allegations of defect in the same products, and as such constitute multiple punishments for the same alleged conduct resulting in deprivation of Defendant's property without due process of law and will result in unjustified windfalls for Plaintiffs and Plaintiff's counsel, in violation of the Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States and similar protections afforded by the Virginia and Indiana state constitutions, and that of any other state whose law is deemed to apply in this case.

TWENTY-SEVENTH SEPARATE DEFENSE

Any claim for punitive damages against Defendant cannot be maintained because an award of punitive damages under current Virginia law, and any other state's law deemed to apply to this action, would or may be void for vagueness, both facially and as applied. Among other deficiencies, there is or may be an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it may permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fifth and Fourteenth Amendments to the United

States Constitution, the due process provisions of the Virginia state constitution, and the common law and public policies of Virginia and similar protections afforded by any other state whose law is deemed to apply in this case.

TWENTY-EIGHTH SEPARATE DEFENSE

To the extent that the law of Virginia and any other state whose law is deemed to apply in this case, permit punishment to be measured by the net worth or financial status of Defendant and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious, and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, allows punishment to be imposed based on lawful profits and conduct of Defendant in other states, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, the state laws and constitutional provisions of Virginia and similar protections afforded by any other state whose law is deemed to apply in this case.

TWENTY-NINTH SEPARATE DEFENSE

The product at issue was in compliance with all applicable codes, standards, regulations and specifications established by the United States and/or the State of Virginia, or by any agencies of the United States and/or the State of Virginia, and accordingly the product at issue is presumed to be non-defective.

THIRTIETH SEPARATE DEFENSE

This Court does not have personal jurisdiction over Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson & Johnson International, or DePuy International Limited.

THIRTY-FIRST SEPARATE DEFENSE

Defendant hereby raises, asserts, and preserves its defense of improper venue or *forum non conveniens*.

THIRTY-SECOND SEPARATE DEFENSE

Defendant asserts the limitations of prejudgment interest set forth by Virginia Annotated Code §8.01-382 to the extent that Virginia law applies to this matter.

THIRTY-THIRD SEPARATE DEFENSE

Defendant is entitled to the protections and limitations afforded under Virginia law.

THIRTY-FOURTH SEPARATE DEFENSE

Plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design that would have prevented the harm alleged by Plaintiff without substantially impairing the usefulness or intended purpose of the product.

THIRTY-FIFTH SEPARATE DEFENSE

Defendant reserves the right to raise such further and additional defenses as may be available upon the facts to be developed in discovery and under other applicable substantive law.

PRAYER

WHEREFORE, Defendant respectfully prays as follows:

1. That Plaintiff take nothing by reason of the Complaint;

2. That the Complaint against Defendant be dismissed in its entirety;

3. That Defendant recovers its reasonable costs of suit incurred in defense of this action; and

4. For such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Defendant demand trial by jury on all issues so triable.

By: /s/ William F. Devine
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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of May, 2019, I electronically filed the foregoing in the United States District Court for the Eastern District of Virginia, and a copy will be served by CM/ECF upon:

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